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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,398	01/02/2002	K. Ranji Vaidyanathan	003248.00041	8382

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EXAMINER	
SCHILLINGER, ANN M	
ART UNIT	**PAPER NUMBER**
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,398	VAIDYANATHAN ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,11-15 and 25-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-8,11-15 and 25-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 27, 29, 31, 32, 34, 36, and 37 are rejected under 35 U.S.C. 103(a) as being anticipated by Vanderstraeten (US Pat. No. 5789017) in view of Klawitter et al. (US Pat. No. 4,000,525). Vanderstraeten discloses the following of claim 1: a biocompatible implant for surgical implantation comprising: a matrix comprising a resorbable substrate composition selected from the group consisting of polybutyleneterephthalate and polyethyletherketone (col. 2, lines 21-22; col. 3, lines 18-21). Vanderstraeten does not disclose the pore size and porosity volume claimed. However, Klawitter et al. discloses these values in col. 1, line 45 through col. 2, line 3, and in col. 3, lines 24-38 for the purpose of creating an implant of high interconnectivity to accept bone ingrowth. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use these values of pore size and porosity in order to create an implant of high interconnectivity that is able to accept bone ingrowth.

Vanderstraeten discloses the following of claim 2: the implant of claim 1 wherein the natural bone structure substantially replaces the implant after the period of time (col. 4, lines 2-8).

Vanderstraeten discloses the following of claim 4: the implant of claim [[3]] 1 wherein the implant also includes a growth-enhancing composition for stimulating new tissue growth at the site of implantation (col. 3, line 61 through col. 4, line 8).

Vanderstraeten discloses the following of claim 27: the implant of claim 4 wherein the growth-enhancing composition is a coating over at least a portion of the matrix (col. 3, lines 18-21).

Vanderstraeten discloses the following of claim 29: a biomedical implant comprising: a porous structure formed from a material comprising polybutyleneterephthalate (col. 3, lines 18-21), the porous structure having a porosity between about 25% to about 70% by volume (col. 2, lines 15-25) and a pore size between about 100 to about 2400 micrometers (col. 4, lines 36-42), the porous structure providing load-bearing support for natural bone structure for a period of time (col. 1, lines 20-44); and a composition for enhancing the rate of bone growth, wherein the composition comprises a biocompatible polymer material and a calcium source, and the composition coats at least a portion of the structure or fills at least a portion of the pores of the structure (col. 2, lines 39-53; col. 3, lines 18-21).

Vanderstraeten discloses the following of claim 31: the biomedical implant of claim 29, wherein the calcium source is selected from the group consisting of calcium phosphates and calcium sulfates (col. 1, lines 20-44).

Vanderstraeten discloses the following of claim 32: the biomedical implant of claim 29, wherein the composition for enhancing the rate of bone growth both coats at least a portion of the structure and fills at least a portion of the pores of the structure (col. 3, lines 18-21).

Vanderstraeten discloses the following of claim 34: a biomedical implant comprising: a porous structure formed from a material comprising polyethyletherketone (col. 2, lines 21-22; col. 3, lines 18-21), the porous structure having a porosity between about 25% to about 70% by volume (col. 2, lines 15-25) and a pore size between about 100 to about 2400 micrometers, the porous structure providing load-bearing support for natural bone structure for a period of time (col. 4, lines 36-42); and a composition for enhancing the rate of bone growth, wherein the composition comprises a biocompatible polymer material and a calcium source, and the composition coats at least a portion of the structure or fills at least a portion of the pores of the structure (col. 2, lines 39-53; col. 3, lines 18-21).

Vanderstraeten discloses the following of claim 36: the biomedical implant of claim 34, wherein the calcium source is selected from the group consisting of calcium phosphates and calcium sulfates (col. 1, lines 20-44).

Vanderstraeten discloses the following of claim 37: the biomedical implant of claim 34, wherein the composition for enhancing the rate of bone growth both coats at least a portion of the structure and fills at least a portion of the pores of the structure (col. 3, lines 18-21).

Claims 5, 12, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderstraeten in view of Klawitter et al. in further view of Lin et al. (US Pat. No. 4645503) or Vanderstraeten in view of De Bruijn et al. in further view of Lin et al. Vanderstraeten discloses the invention substantially as claimed, however, Vanderstraeten does not disclose the implant having different degradation rates. Lin et al. discloses an implant with different degradation rates in col. 2, lines 46-57 and col. 5, lines 17-25 for the purpose of creating an implant with the desired physical properties. Therefore, it would have been obvious to one of ordinary skill in the

art at the time the invention was made to give the implant different degradation rates in order to creating an implant with the desired physical properties.

Claims 6, 8, 30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderstraeten in view of Klawitter et al. in further view of De Bruijn et al. (US Pat. No. 6228117). Vanderstraeten discloses the invention substantially as claimed, however, Vanderstraeten does not disclose the specific biocompatible polymer-ceramic composition as described by the Applicant. De Bruijn et al. discloses an implant with different degradation rates in col. 1, lines 37-43 for the purpose of growing bone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to give the specific biocompatible polymer-ceramic composition in order to grow bone.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderstraeten in view of Klawitter et al. in further view of De Bruijn et al. in further view of Vyakarnam et al. (US Pat. No. 6534084). Vanderstraeten and De Bruijn et al. disclose the invention substantially as claimed, however, they do not disclose the use of transforming growth factors. Vyakarnam et al. discloses the use of transforming growth factors in col. 17, lines 37-65 for the purpose of serving as a therapeutic growth agent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to the use of transforming growth factors in order to serve as a therapeutic growth agent.

Claims 11, 13, 15, 25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderstraeten in view of Klawitter et al. in further view of De Bruijn et al. Regarding claims 11 and 25, Vanderstraeten discloses the invention substantially as claimed in col. 2, lines 15-25; col. 2, lines 21-22; col. 3, lines 18-21; col. 4, lines 36-42; and col. 1, lines 20-44.

However, Vanderstraeten does not disclose the specific biocompatible polymer-ceramic composition implanted in vivo as described by the Applicant. De Bruijn et al. discloses such an implant with different degradation rates in col. 1, lines 3-6 and 37-43 for the purpose of growing bone. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to give the specific biocompatible polymer-ceramic composition in order to grow bone.

Vanderstraeten discloses the following of claim 13: the biomedical implant of claim 11 wherein the structure has a porosity between about 50% to 60% by volume (col. 2, lines 15-25) and a pore size between about 150 to about 400 micrometers (col. 4, lines 36-42).

Vanderstraeten discloses the following of claim 15: the biomedical implant of claim 11 wherein the composition for enhancing the rate of bone growth includes a calcium source (col. 2, lines 39-42). 16-24.

Vanderstraeten discloses the following of claim 28: the method of claim 25 wherein the growth-enhancing composition provides a coating over at least a portion of the biocompatible substrate (col. 3, lines 18-21).

Claims 33 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vanderstraeten in view of Klawitter et al. in further view of Dunn et al. (US Pat. No. 4655777). Vanderstraeten discloses the invention substantially as claimed, however, Vanderstraeten does not disclose the use of polycaprolactone. Dunn et al. teaches the use of polycaprolactone in col. 2, lines 40-53 for the purpose of utilizing its degradation times and degree of control of degradation. Therefore, it would have been obvious to one of ordinary skill in the art at the time

the invention was made to use polycaprolactone in order to utilize its degradation times and degree of control of degradation.

Response to Arguments

Applicant's arguments with respect to claims 1, 4-8, 11-15, and 25-38 have been considered but are moot in view of the new ground(s) of rejection.

Regarding the Applicants arguments that claim 2 does not disclose the natural bone replacing the implant over time, Vanderstraeten discloses the bone ingrowth which will inherently replace substantial portions of the implant.

Regarding the Applicants arguments addressing the priority date of the claims in the present application, Applicants contend that the presentation given by Dr. Vaidyanathan would not constitute a printed publication. However, Applicant may want to provide evidence as to how Dr. Vaidyanathan's circumstances are similar to the case law cited. Additionally, there is no indication that the presentation's audience was subject to any confidentiality restrictions. Therefore, the priority date of the present invention is January 2, 2002.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
April 27, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER